DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 31, 2015

Navilyst Medical, Inc.
Ms. Wanda Carpinella
Director, Regulatory Affairs
26 Forest Street
Marlborough, MA 01752

Re: K150527
Trade/Device Name: Xcela Power Injectable PICC
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: II
Product Code: LJS
Dated: February 27, 2015
Received: March 02, 2015

Dear Ms. Carpinella:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K150527

Device Name
Xcela Power Injectable PICC

Indications for Use *(Describe)*

The Xcela Power Injectable PICC is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media. Maximum power injection flow rate:
4F Single Lumen, 45 cm - 4 mL/sec
4F Single Lumen, 55 cm - 3.5 mL/sec
5F Single Lumen, 55 cm - 5 mL/sec
5F Dual Lumen, 45 cm - 5 mL/sec
5F Dual Lumen, 55 cm - 4 mL/sec
6F Dual Lumen, 55 cm - 5 mL/sec

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY FOR THE XCELA POWER INJECTABLE PICC

510(K) #: K150527

Date prepared: March 30, 2015

A. Sponsor

Navilyst Medical, Inc
26 Forest Street
Marlborough, MA 01752

B. Contact

Wanda Carpinella
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OR

Brandon Brackett
Specialist II, Global Regulatory Affairs
508-658-7940 brandon.brackett@angiodynamcis.com

C. Device Name

Trade Name	Xcela Power Injectable PICC
Common/Usual Name	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Percutaneous, Implanted, Long-Term Intravascular Catheter
Classification Regulation	21CFR§880.5970, Class II
ProCode	LJS
Classification Panel	General Hospital

D. Predicate Device

Common/Usual Name	Peripherally Inserted Central Catheter (PICC)
Classification Name:	Percutaneous, Implanted, Long-Term Intravascular Catheter
Classification Regulation	21CFR§880.5970, Class II
ProCode	LJS
Classification Panel	General Hospital
PreMarket Notification	K070002, Xcela Power Injectable PICC K133264, NMI PICC III

E. Device Description Intended Use

The Xcela Power Injectable PICC is indicated for short- or long-term peripheral access to the central venous system for intravenous therapy, including but not limited to, the administration of fluids, medications and nutrients, the sampling of blood, and for power injection of contrast media. Maximum power injection flow rate:

- 4 Fr SL, 45 cm-4 mL/sec
- 4 Fr SL, 55 cm=3.5 mL/sec
- 5 Fr SL, 55 cm=5 mL/sec
- 5 Fr DL, 45 cm-5 mL/sec
- 5 Fr DL, 55 cm=4 mL/sec
- 6 Fr DL, 55 cm=5 mL/sec

F. Summary of Similarities and Differences in Technological Characteristics and Performance

When compared to the predicate Xcela Power Injectable PICC (**K070002**), the proposed Xcela Power Injectable PICC incorporates changes that include: addition of an oversleeve to the extension tube, a new non-valved luer design, and inclusion of maximum flow rates into the indication statement – the same changes that were made to the predicate NMI PICC III in **K133264**. With the addition of these changes, the only difference between the proposed Xcela Power Injectable PICC and the predicate NMI PICC III (**K133264**) is that the catheter shaft of the proposed device does not contain Endexo – a polymer blended into the catheter shaft that reduces the accumulation of thrombus – whereas the predicate NMI PICC III's catheter shaft does. Please note: the predicate Xcela Power Injectable PICC (**K070002)** also does not contain Endexo.

All other aspects of the proposed devices, including packaging and sterilization, are identical to those of the predicate; no other changes are being proposed herein. In brief, both the proposed and predicate devices are:

- intended for short- or long-term peripheral access to the central venous system for intravenous therapy, blood sampling, and power injection of contrast media;
- available in single and multi-lumen configurations in a wide range of sized from 4F to 6F outside catheter diameter;
- rated for maximum power injector settings up to 325 psi;
- rated for maximum power injection flow rate up to 5 ml/second based on model; and
- available kitted with a range of procedural accessories for user convenience.

G. Performance Data

The XP is substantially equivalent to Navilyst predicate devices based on comparison of technological characteristics and the results of non-clinical tests which included the performance evaluation conducted in accordance with the following FDA guidance documents, international standards, and testing which included:

- EN ISO 10555-1:2009, *Sterile, Single use intravascular catheters – Part 1: General Requirements*
- EN ISO 10555-3:1997 Corrigendum 1:2002, *Sterile, Single-Use Intravascular Catheters – Part 3: Central Venous Catheters*
- FDA's "*Guidance on Premarket Notification [510(K)] Submissions for Short-Term and Long-Term Intravascular Catheters dated March 16, 1995*"

H. Conclusion

The results of the non-clinical testing and a comparison of similarities and differences demonstrate that the proposed and predicate devices are substantially equivalent.